



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/415,890	10/08/1999	BORJE S. ANDERSSON	UTXC:528-1	5425

7590 04/24/2003

ARNOLD WHITE & DURKEE
P O BOX 4433
HOUSTON, TX 77210

EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/24/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Art Unit: 1616

Applicant's election of Group IV, with aqueous Lipid emulsion species in Paper No. 19 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 16-23, 26-92, 94-96, 100-115, 123-132 and 138-140, 144-149 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 19.

Applicant states claims 93-149 are pending. That is incomplete; 16-23, 26-149 are pending, since amendment ^A cancelled 1-15, 25 and 26 and no further cancellation was done. The pending claims are all subject to double patenting claims are all subject to double patenting considerations, even those withdrawn, since these claims are still alive. Claims 144-149 are drawn to non-elected species; no aqueous lipid emulsion is present, or the solvent is an infusion fluid.

Claim 98 clearly indicates a solution, not a solvent, thus use composition, not the so ~~uent~~ vehicle, is presented.

Claims 93, 97-98, 116-122, 133-137, 141-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection to virtually is maintained.

[¶] "Virtually eliminated" is not evident to examiner – the terminology can mean according to the specification, 50% removal, or 99+% removal. The declaration does

Art Unit: 1616

not put language into the specification. Examiner appreciates the ~~Federal~~ Register solvent guidance.

Claims 93, 97-98, 116-122, 133-137, and 141-143 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no method of Preparation examiner can discern, inclusive of all of the cited referenced pages of the current and 12/21/01 amendments in which support for claims as amended was identified, where a drug was added to the solvent vehicle, all preparation methods were initiated with dissolving the pimaricin compound, difficultly stable, in a solvent, followed optionally with co solvents, and then in commonly accepted aqueous injectable solvent vehicles. We find no description of mixing 2 solvents, removing acid and/or aprotic solvent, (claim 93) and then reconstituting with an aqueous solution (claims 97, 98). The issue is not seen as trivial, since the dissolution and stability was not evident in the specification in some of the single solvent tests. One would require Leap of faith to go from the specification, focusing on parenteral vehicles for pimaricin, to dissolution of pimaricin after the completed solvent vehicle as prepared at claim 93, or reconstituted product of claim 97. The specification, as far as applicant has identified and examiner has perused, does not provide support for the claims.

Claims 93, 99, 116, 117, 133, 141 are rejected under 35 U.S.C. 102(b) as being anticipated by Szoka Jr. 5549910 or Szoka, Jr. 5277914.

Art Unit: 1616

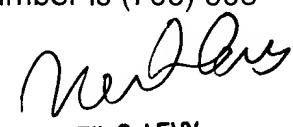
Szoka obtains dipolar aprotic solvents, (col. 3, top) DMSO, mixes with an aqueous pharmaceutical secondary solvent a lipid solution (col. 4, B) solvent is then, virtually or, completely, eliminated, by centrifugation, dialysis – and the like (col. 6, lines 3-6). The method includes polyene antifungals, primaqricin (col. 3, 4A) as of instant claim 99 the lipid solution.

Applicant's arguments filed on 2/11/03 and 9/24/02 have been fully considered but they are not persuasive. Applicant's statement of support for amended claims is found to incorporate pimaricin, without exception, yet Pimaricin is not claimed, except at claim 99. The statutory status of claims is also not in accord with the file; see summary page 1 of this action only claims 1-15, 24 and 25 had been cancelled, to date. The traversal of species requirement is noted, and is seen as request for the non-elected species to be searched if the elected emulsion is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703) 308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


NEIL S. LEVY
PRIMARY EXAMINER